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09/990,080	11/21/2001	Gregg B. Morin	018/258C	2136

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EXAMINER	
WALICKA, MALGORZATA A	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,080	MORIN, GREGG B.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-22* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 10* is/are allowed.

6)☒ Claim(s) *2-7,9-17,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Amendment and Response to Office Action under 37 CFR § 1.111 filed on July 12, 2005 containing amendments to the specification and claims is acknowledged. Claim 8 has been previously cancelled. Claims 1-7 and 10-21 are amended; new claim 22 has been added. Claims 1-7 and 9-22 are pending. After the current amendment, claims 1-7, 9-17 and 21 are under examination. Claims 18-20 and 22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

DETAILED ACTION

1. Restriction election

The newly filed claim 22 is directed to the invention which is new. Newly submitted claim 22 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claim is directed to the use of a DNA encoding polypeptide of claim 2. Thus, the claim is directed to the use of product different than examined thus far.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 22is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Objections

2.1. Specification

Table 1 is objected to for lack of columns describing mutants' ability to bind RNA and human telomeres. Such mutants are specifically claimed in claims 6 and 7.

3. Rejections

3. 1. 35 USC, section 112, second paragraph

Claims 1-3, 5-7, 16 and 17 were rejected in the previous Office Actions for the use of the limitation "deletions consisting essentially of".

Rejection withdrawal

Rejection of claim 1 is withdrawn, because the claim does not recite the term "consisting essentially of".

Rejection of claim 4 and 5 is withdrawn, because the claims have been amended.

Rejection of claim 2 for recitation "consisting essentially of" is withdrawn, because the definition of the term consisting of given in REMARKS as used in claim 3 is accepted .

Claims 3, 5, 16 and 17 are still rejected under this paragraph. It is unknown which additional amino acids are included and excluded from the scope of deletions recited by the claims. The phrase "deletions consisting essentially of" is for the purpose of searching and applying prior art construed as equivalent to "comprising"; see MPEP 2111.03 "Transitional Phrases".

Traversing the rejection of claims 1-3, 5-7, 16 and 17 Applicants write in their Remarks of July 12, 2005, page 1o, last paragraph,

"This means that the deletion(s) of residues from SEQ ID NO: 2 may be a few amino acids shorter or longer than the specified range, as long as the polypeptide having the deletions (s) still lacks telomerase catalytic activity when associated in telomerase RNA component."

This definition cannot be accepted by one having skills in the art, because although decreasing the number of deleted amino acid may in some cases restore the telomerase activity, broadening the deletion will not. Thus, although the definition could apply to shortening the recited deletions, it cannot apply to their broadening.

The amended claims 2 and 3 are rejected under this paragraph, because it is unclear if the protein recited must consist essentially of at least 500 amino acids of SEQ iD NO:2 befor or after making the recited deletions. Since the claims recite deletions that include or deletions consisting essentially of (i.e. comprising) certain amino acid residues, if this recitation is to the length only before this deletion the claims reada on any protein comprising an epitope of SEQ ID NO:2.

3.2. 35 USC, section 112, first paragraph

3.2.1. Lack of written description

3.2.1.1. Rejection for new matter

Claims 1-7 and 16-17 were rejected in the Office Action of January 13, 2005, previous action, under 35 U.S.C. 112, first paragraph, for new matter.

Rejection withdrawal

Rejection of claim 1, 4 and 5 is withdrawn, because the claims have been amended.

Rejection caused by current amendment

Claims 2, 3, 6, and 7 are rejected for new matter introduced by the current amendment. The claims are directed to a polypeptide consisting essentially of at least 500 consecutive amino acids of SEQ ID NO: 2 containing deletions listed under a)-g) of the claims, wherein said polypeptide lacks telomerase activity, but elicits an antibody response against hTRT when used to immunize a rabbit or mouse.

Neither the specification nor the claims as originally filed teach any variant of human telomerase to be used for production of antibodies. In their current amendment to the specification Applicants added description of production of antibodies based on US Patent 6,168,178, which is incorporated by reference. The inserted text provides enablement for preparation of antibodies against HTRT, however, because the patent is based on the application that does not disclose variants of the instant application, the inserted text does not provide for written description of the matter claimed in the current version of claims 2, 3, 6 and 7. The instant application does not claim priority to the US application 08/974,549 on which said patent was issued. Furthermore Dr. Morin, the only inventor on the instant application is not the inventor on the patent. In conclusion, claims 2, 3, 6 and 7are rejected because one skilled in the art is not convinced that Applicants were in possession of the claimed invention at the time application was filed.

3.2.1.1. Rejection for lack of structure and/or function

Rejection withdrawal

Rejection of claim 1, and 10 is withdrawn, because claim 1 has been amended.

Rejection not withdrawn or caused by amendment

Claims 2, 3, 4-7 and 12 are rejected as lacking sufficient written description. The Claims are directed to the following large and variable genera of polypeptides:

claim 2 a polypetide that inhibits human telomerase and comprises at least 500 consecutive amino acids from a sequence encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ ID NO: 1; but which contains one or more deletions, which include:

a) residues 560-565,

b) residues 930-934,

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116,

wherein said polypeptide lacks telomerase catalytic activity, but elicits an antibody response against hTRT when used to immunize a rabbit or mouse;

claim 3 a polypetide that comprises at least 500 consecutive amino acids of SEQ ID NO: 2, but which contains one or more deletions, each of which consists essentially of, i.e. comprising:

a) residues 560-565,

b) residues 930-934,

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116,

wherein said polypeptide lacks telomerase catalytic activity, but elicits an antibody response against hTRT when used to immunize a rabbit or mouse;

claim 4 a polypeptide lacking telomerase enzyme activity, wherein said polypeptide comprises full-length hTRT except for one or more deletions (s) that include:

a) residues 560-565,

b) residues 930-934,

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116;

claim 5 a polypeptide lacking telomerase enzyme activity, wherein said polypeptide comprises full-length hTRT (SEQ ID NO: 2) except for one or more deletions consisting essentially of, i.e., comprising residues 560-565, 930-934, 323-450, 635-660, 748-766, 1055-1071, or 1084-1116. of SEQ ID NO: 2, wherein said polypeptide lacks telomerase catalytic activity;

claim 6 a polypetide of claim 2 which binds human telomerase RNA components but lacks processive telomerase activity;

claim 7 a polypetide of claim 2, wherein such polypeptide binds human telomeres but lacks processive telomerase activity;

Claims 2-3, 6-7 and 12 are lacking written description of structure of polypeptides containing deletions consisting essentially of residues 560-565 or 930-934 and deletions consisting essentially of residues 560-565, 930-934, 323-450, 635-660, 748-766, 1055-1071, or 1084-1116 of SEQ ID NO: 2. The disclosure provides representative species that are polypeptides identified by SEQ ID NO: 2, wherein amino acids residues 560-565, 930-934, 323-450, 637-660, 748-766, 1055-1071, or 1084-1116 of SEQ ID NO: 2 are deleted. Providing these species is insufficient for identifying the structure of the all species of the genus, because of lack of the definition the term "consisting essentially of"; see response to the rejection under 112, second paragraph above. It is unknown, therefore, which additional amino acids are included and excluded from the length scope of deletions that are to be present in the claimed polypeptides. On page 4, line 36 (of substitute specification) one reads "Thus in some embodiments the mutation is a

deletion of at least one, typically at least 10 and often at least 25, at least about 50, or at least 100 amino acid residues relative to a naturally occurring hTRT." On the other hand, on page 2 in Summary, one reads "In one embodiment, the hTRT polypeptide has a deletion of at least 25 residues." These description are not consistent and are not a definition of "consisting essentially of". For that reason the transitional phrase "consisting essentially of" is understood as "comprising"; see MPEP 2111.03. "Transitional Phrases". See also the above rejection under 35 USC section 112, second paragraph.

Furthermore, it is also unknown what amino acid sequence comprsing at least 500 contiguous amino acids of SEQ ID NO:2, except for the listed deletions, ensures the function of eliciting an antibody response against hTRT. Although the size of an epitope may comprise only 5 amino acids, it is important that the epitope be accessible to an antibody in the three dimensional structure of hTRT. Furthermore peptides which induce an antibody response to an antigen when used alone often not do so when inserted within a large polypeptide sequence.

Claim 4 and 5 lack description of structure for the reasons explained above, and the claims also suffers from lack of function.

In summary, claims 2-7 and 12 are rejected because one of skills in the art is not convinced that Applicants were in possession of the claimed invention at the time the application was filed.

3.2.2. Scope of enablement

Claims 9, 11, 12, 13-17 and 21 were rejected for lack of enablement for the scope of invention. The reasons for rejection were explained in the previous action. This rejection is not withdrawn, although the scope of the claims has changed. Claims are now limited to human telomerase.

Claim 13 and dependent claims 9, 14 –17, directed to the protein peptide or peptide mimetic that inhibit any human telomerase and claims 11 and 21 directed to the method of their use. The specification why being enabling for inhibiting human telomerase reverse transcriptase of SEQ ID NO: 2 by polypeptides disclosed by applicants (see Table 1 of the specification) does not reasonably provide enablement for any protein, peptide or peptide mimetic that inhibits human telomerase. Lack of sufficient structural characteristics of inhibitors of human telomerase makes the probability of success in obtaining the claimed invention rather low. Thus, to make and use the claimed invention one skilled in the art is forced to do research outside the realm of routine experimentation. If a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should precede so that the claimed species have the functionality intended by Applicants i.e. to inhibition of any telomerase. The provision of inhibitors (Table 1) taught by the specification and human telomerase of SEQ ID NO: 2 fails to provide such guidance of the structure of any polypeptide which remain encompassed within the scope of the rejected claims.

Examiner concludes that without the further guidance on the part of Applicants in regards to structure of the claimed inhibitors and origin and structure of telomerase to be inhibited, experimentation left to those in the art is improperly extensive and undue.

Claims 2-3, 6-7 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide polypeptides identified by SEQ ID NO: 2, wherein amino acids residues 560-565, 930-934, 323-450, 637-660, 748-766, 1055-1071, or 1084-1116 of SEQ ID NO: 2 are deleted, does not reasonably provide enablement for the large and variable genera of polypeptides :

claim 2 a polypetide that inhibits human telomerase and comprises at least 500 consecutive amino acids from a sequence encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ ID NO: 1; but which contains one or more deletions, which include:

a) residues 560-565,

b) residues 930-934,

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116,

wherein said polypeptide lacks telomerase catalytic activity, but elicits an antibody response against hTRT when used to immunize a rabbit or mouse;

claim 3 a polypetide that comprises at least 500 consecutive amino acids of SEQ ID NO: 2, but which contains one or more deletions, each of which consists essentially of, i.e. comprising:

a) residues 560-565,

b) residues 930-934,

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116,

wherein said polypeptide lacks telomerase catalytic activity, but elicits an antibody response against hTRT when used to immunize a rabbit or mouse;

claim 6 a polypetide of claim 2 which binds human telomerase RNA components but lacks processive telomerase activity;

claim 7 a polypetide of claim 2, wherein such polypeptide binds human telomeres but lacks processive telomerase activity;

and the method of their use (claim 12).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to the structure of large number of peptide inhibitors of human telomerase of human telomerase; see the above rejection for lack of written description.

Regarding claims 2-3 and 12, while methods of gene cloning and gene structure manipulations are well known in the relevant art, and skills of the artisans highly developed, one skilled in the art is not able to make any polypeptide consisting essentially of at least 500 consecutive amino acids of SEQ ID NO:2, except for that it comprises the listed deletions, wherein said polypeptide elicits an antibody response against hTRT. Applicants do not teach what amino acid sequence comprsing at least 500 contiguous amino acids of SEQ ID NO:2, except for the listed deletions, ensures the function of eliciting an antibody response against hTRT. Without guidance on the structure of claimed polypeptides the experimentation left to those skilled in the arts has a low probability of success. It is so because peptides which induce an antibody response to an antigen when used alone often not do so when inserted within a large polypeptide sequence. In addition, it is important that the epitope be accessible to an antibody in the three dimensional structure of hTRT. The specification does not provide any guidance regarding theses two aspects of structure of the claimed inventions, thus the experimentation imposed on those having skills in the art is undue.

Regarding claims 6 and 7 applicants do not provide the teachings which of the polypeptides of claim 2 binds human telomerase RNA or human telomers but lacks procesive telomerase activity. Thus, to make and use the claimed invention one skilled in the art is forced to do research outside the realm of routine experimentation. If a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that the claimed species have the functionality intended by Applicants. The provision negative mutants having the amino acid sequence derived from SEQ ID NO: 2 by deleting the amino acids 192-450 or 637-660 or 638-66 or 748-766 or 748-764 or 1055-1071 or 1084-116 or 650-565 fails to provide such guidance of the structure of any polypeptide which remain encompassed within the scope of the rejected claims.

Foreseeing the rejection of amended claims 6 and 7 Applicant argues that the skilled reader may herself readily determine whether a product has this function; REMARKS page 10, line 7. What Applicants expect from one skilled in the art is "a result that one might achieve if one made that invention"; see Eli Lilly, 119 F.3d at 1568. 43 USPQ2d at 1406 as quoted in MPEP page 2100-173 paragraph (2).

In summary, without the further guidance on the part of Applicants in regards of structure of the claimed polypeptides, experimentation left to those in the art is improperly extensive and undue.

4. 35 USC section 112, paragraph 6

Claims 13, and dependent claims 9, 11, 14, 15, 16 17 and 21 use the terms

means and an associated function, i.e., inhibiting human telomerase).

In his Remarks of October 8, 2004, page 17, second paragraph, Applicant states that claiming an invention in terms of means plus function is explicitly provided for in 35 USC § 112, sixth paragraph and the claims are definite and fully described because:

> "*a means for inhibiting telomerase activity* as referenced in the claims are exemplified sufficiently in the specification and in the dependent claims so that the skilled reader will understand what structure is meant. Accordingly, the claims meet the requirements of § 112 paragraph 6 of § 112 paragraph. Withdrawal of these rejections [of claims 13 and dependent claims] is respectfully requested."

This argument of Applicant's has been carefully analyzed, but is found not persuasive because one skilled in the art can easily recognize that the scope of the claims covering any inhibitor that is protein, peptide or peptide mimetic and that has a means for inhibiting human telomerase is lacking support in the disclosure.

Although the proper test for meeting the definiteness requirements is that the corresponding structure of a means plus function limitation need only be disclosed in the specification in a way that one skilled in the art will understand what structure will perform the recited function (MPEP page 2100-224 of May 2, 2004 revision, left column, second paragraph). The specification clearly fails to disclose specifically which structures have the specific function. Furthermore, the specification fails to provide sufficient disclosure such that a skilled artisan would recognize "equivalents" of structures disclosed in the specification. Equivalents for the purposes of 112 6th paragraph are clearly not so broad as to be any structure having the function. The

specification must clearly define identifying characteristics of such equivalents such that a skilled artisan would recognize what structures are encompassed in the claim. The specification clearly fails to do so as it recites no identifying characteristics of such inhibitors. the broad scope of claim 13 and dependent claims does not correspond with the structures disclosed in the specification. The specification discloses 18 polypeptides that are modifications of human telomerase reverse transcriptase sequence of SEQ ID NO: 2 (Table1). The inhibitors are obtained by deletion of:

a) residues 560-565,

b) residues 930-934,

c) residues 326-415.

d) residues 637-660,

e) residues 748-766,

f) residues 1055-1071, or

g) residues 1084-1116

some additional polypeptides that can be derived from SEQ ID NO: 2 by deleting

c) at least 10 consecutive amino acids from residues 323-450.

d) at least 10 consecutive amino acids from residues 637-660,

e) at least 10 consecutive amino acids from residues 748-766,

f) at least 10 consecutive amino acids from residues 1055-1071, or

g) at least 10 consecutive amino acids from residues 1084-1116.

These polypeptides do not exhibit reverse transcriptase processive activity, and one skilled in the art recognizes they can be used as inhibitors of human telomerase reverse transcriptase of SEQ ID NO: 2.

As to the whole scope of the claims, **"the invocation of 35 U.S.C. 112, sixth paragraph does not exempt an applicant from compliance with 35 U.S.C. 112, first and second paragraphs. See *Donaldson*, 16 F.3d at 1195, 29 USPQ2d at 1850",** MPEP page 2100-224 of May 2, 2004 revision, right column, second paragraph, line 19). Applicant does not comply with written description requirement and definiteness requirement because:

1. the disclosure fails to describe the structure of equivalents of the above structures having the inhibitory property against human telomerase of SEQ ID NO: 2; and a skilled artisan would not recognize what structures are encompassed.
2. Applicants do not define (see the above rejections under 35 USC, 112 second and first paragraphs) what is the meaning of the term "deletions consisting essentially of" in relation to deletions of:

   a) residues 560-565,

   b) residues 930-934,

   c) residues 323-450.

   d) residues 637-660,

   e) residues 748-766,

   f) residues 1055-1071, or

g) residues 1084-1116; and

3. it is not clear from the specification that the specific structures listed in applicants response correspond to the means for inhibiting as recited in claim 13.

For the reasons given in points 1-3 above, claims 13-17and the method claims 11 and 21 should be rejected for lack of written description and for being indefinite.

In response to the rejection Applicants write on page 12, 5th paragraph of REMARKS of July 12, 2005:

"Of course, 1.112 ¶ 6 explicitly invokes the species described in the specification, and so the claims cannot lack literal support if correctly worded. The undersigned understands from the interview that the rejection can be taken as a request that applicant point to the species in the specification that are referred to, consistent with MPEP § 2181 (IV).

Telomerase inhibition means listed in the specification are mutants of the hTRT sequence (SEQ ID NO: 2) that contain at least one deletion of 10 amino acids or more listed in Table 1 as having "-" telomerase activity (page 8 of the substitute specification), or the PGRN constructs corresponding thereto (Table 1). Also listed are peptides or peptide mimetics having an amino acid sequence consisting essentially of SEQ ID NO: 3, 4 and 5 (page 9)."

Applicant's arguments have been fully considered but are found not persuasive for the following reasons.

1. When an applicant invokes 112, 6th paragraph the scope of the claim is interpreted as covering those structures explicitly described in the specification as having the recited function and equivalents thereof (see MPEP 2181, Part II). The term equivalents in this phrase is clearly not so broad as to include any structure having the function but is limited to corresponding structure. For example, phosphatase 2A inhibits human telomerase (Li H. et al. *Protein Phosphatase 2A Inhibits Nuclear Telomerase Activity in Human Brest Cancer Cells*, J. Biol. Chem, 1997, July 4, 272, 16729-16732), but does not have a corresponding structure and is not supposed to be included in the scope of the claims. The specification must define what the identifying characteristics of a corresponding structures are. Use of 112, 6th paragraph claiming does not exempt applicants from describing the invention as required by 112, 1st paragraph.

2. The detailed structure of the pGRN constructs is not disclosed, therefore these construct cannot be included in the scope of the claims as Applicant seems to request in his REMARKS.

3. Also the term consisting "essentially of " is not identified unequivocally, as discussed above in rejection under 35 USC 112, second paragraph above.

4. The structure of mimetics is not the same as that of mutants or fragments of SEQ ID NO: 2 and none of the structures identified by applicants within the

specification are peptide mimetics nor is it clear what mimetics of the species identified by applicants would be considered by a skilled artisan to be equivalents of the disclosed species.

In addition, the structures of polypeptides claimed in claims 14 and 15, and their equivalents, are lacking identification in the specification. Applicants do not teach the structure of polypeptides, peptides and mimetics that lack the sequence fragments which is responsible for binding telomerase, or its modification, to telomerase RNA component or human telomere. Instead Applicant argues that the skilled reader may herself readily determine whether a product has this functionon empirical basis; REMARKS page 10, line 7. One skilled in the art recognizes that what she is expected from is "a result that one might achieve if one made that invention"; see Eli Lilly, 119 F.3d at 1568. 43 USPQ2d at 1406 as quoted in MPEP page 2100-173 paragraph (2). However, written description requirement is not satisfied by merely providing "a result that one might achieve if one made that invention". Thus, the Applicant does not meet either the requirements of 112 1th or 112 2th paragraphs.

4. 35 USC section 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6, 846,662, entitled *Vertebrate Telomerase Genes and Proteins and Uses Thereof*, issued to Killian et al. Jan, 25, 2005, with valid priority to Sept. 9, 1997. The patent discloses splice variant of human telomerase that are catalytically inactive, among others the variant of SEQ ID NO: 46 lacking amino acids 711-722 of SEQ ID NO:2 i.e., reverse transcriptase motive A, but retaining ORF; see column 36, line 65. SEQ ID NO:46 identifies telomerase splice variant which is inactive and maybe for inhnibition of human telomerase of SEQ ID NO:2. The patent teaches inhibitors of telomerase activity in column 22, chapter III; see particularly lines 19-30.

4. Conclusion

Claims 2-7, 9, 11-17 21-22 are rejected; claims 1 and 10 are allowed. The following is the examiner's reason for allowing claim 1 and 10. Applicants disclose inactive mutants of human telomerase having inhibitory action on the enzyme with potential application in treatment of cancer. The invention is novel and nonobvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent Examiner

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